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PARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

November 28, 2000

**WARNING LETTER**

**CIN-WL-5248-00**

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

Lyle E. Brumfield, President and Owner
Brumfield Enterprises, Inc.
301 Buttermilk Pike
Fort Mitchell, KY 41017-2138

Dear Mr. Brumfield:

Our review of the labels for the various flavors of Graeter's FAMOUS FRENCH POT ICE CREAM in half gallon size containers manufactured by your firm reveals that they cause the products to be in violation of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), Part 101- Food Labeling.

The products are misbranded within the meaning of Section 403(q)(1) of the Act in that their labels fails to bear nutrition labeling as required by 21 CFR 101.9 and they are not exempt from this requirement.

We request that you take prompt action to correct these violations. Failure to achieve prompt corrections may result in enforcement action such as seizure being initiated by FDA without further notice.

The above violations are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject the food products to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

Please advise us in writing within fifteen (15) working days of receipt of this letter of the specific actions you have taken to correct the violations along with copies of the revised labels. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which corrections will be completed.

We received your letter in response to the Inspectional Observations (other than labeling violations) listed on the Form FDA 483 that was issued to management at your firm at the close of the FDA inspection on October 31, 2000. The steps you have taken to correct the deficiencies listed on the Form FDA 483 appear to be adequate. Your letter dated October 31, 2000 will be made a permanent part of the Establishment Inspection Report File for your firm.

Your reply should be sent to the Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237 to the attention of Evelyn D. Forney, Compliance Officer.

Sincerely,

for Henry L. Fielden
District Director
Cincinnati District

Cc: Attn: President or General Manager
Graeter's, Inc.
2145 Reading Road
Cincinnati, Ohio 45202